Supreme Court, U.S.
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No. 03-

IN THE

Supreme Court of the United States

ALLERGAN, INC., AND ALLERGAN SALES, INC.,
Petitioners,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD., ALCON UNIVERSAL, LTD., AND BAUSCH & LOMB INCORPORATED,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

The Drug Price Competition and Patent Term Restoration Act of 1984 authorizes generic drug manufacturers to seek approval from the Food and Drug Administration to market generic versions of previously approved drugs through Abbreviated New Drug Applications, or ANDAs. That Act also amended the Patent Act by adding § 271(e)(2), which provides that:

> It shall be an act of infringement to submit—
>
> . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

The question presented is:

Whether § 271(e)(2) permits a patentee to bring an infringement action upon the filing of an ANDA "for a drug . . . the use of which is claimed in a patent," as the plain language of the statute states, or whether such an action can only be brought only upon the filing of an ANDA "for a drug . . . the use of which is claimed in a patent *and is listed in the ANDA*," as the Federal Circuit ruled below.

PARTIES TO THE PROCEEDINGS

All parties to the proceedings are listed in the caption to this petition. Allergan Sales, Inc. is now Allergan Sales, LLC. Allergan, Inc. is the sole shareholder of Allergan Sales, LLC. Allergan, Inc. does not have any parent corporation and no publicly traded company owns 10% or more of its stock.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDINGS	ii
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
JURISDICTION	1
STATUTORY PROVISION INVOLVED	1
STATEMENT OF THE CASE	1
A. Statutory Background	3
B. "Off-Label" Use Of FDA-Approved Drugs	6
C. Petitioner's Method Of Use Patents	7
D. Petitioner's Infringement Claims	8
E. The District Court's Decision	9
F. The Disposition Of Petitioner's Appeal	10
REASONS FOR GRANTING THE PETITION	13
I. PROPER INTERPRETATION OF § 271(e)(2) IS A QUESTION OF EXCEPTIONAL IMPORTANCE TO THE PUBLIC HEALTH AND SAFETY	14
A. The Federal Circuit's Controlling Interpretation Of § 271(e)(2) Severely Undermines Financial Incentives For Developing Important New Uses For Existing Drugs And Could Disrupt Patient Care	14

TABLE OF CONTENTS – continued

	Page
B. The Concurring Opinions Below Confirm The Importance Of The Issue Presented	19
II. THE FEDERAL CIRCUIT'S CONTROLLING INTERPRETATION OF § 271(e)(2) IS WRONG	21
A. The *Warner-Lambert* Panel's Interpretation Is Inconsistent With The Statute's Plain Language	21
B. Interpreting § 271(e)(2) In Accordance With Its Plain Terms Is Consistent With Congressional Intent	23
C. The Patent Certification Provision And Its Legislative History Do Not Override The Plain Language Of § 271(e)(2)	26
CONCLUSION	30

TABLE OF AUTHORITIES

CASES Page

Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 106 F. Supp. 2d 696 (D.N.J. 2000) 18
Eli Lilly & Co. v. *Generix Drug Sales, Inc.*, 460 F.2d 1096 (5th Cir. 1972) 15
Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) 3
Ethicon Endo-Surgery v. *U.S. Surgical Corp.*, 855 F. Supp. 1500 (S.D. Ohio 1994) 17
Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002) 19
Freytag v. *Commissioner*, 501 U.S. 868 (1991) ... 23
GenDerm Corp. v. *Ferndale Labs., Inc.*, 32 USPQ2d 1567 (E.D. Mich. 1994) 17
Glaxo, Inc. v. *Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) 24
Hybritech Inc. v. *Abbott Labs.*, 4 USPQ2d 1001 (C.D.Cal.1987), *aff'd*, 849 F.2d 1446 (Fed.Cir.1988) 17
Neuromedical Sys., Inc. v. *Neopath, Inc.*, No. 96 Civ. 5245 (JFK), 1998 WL 264845 (S.D.N.Y. May 26, 1998) 17
Pfaff v. *Wells Elecs., Inc.*, 525 U.S. 55 (1998) 23
Reedco, Inc. v. *Hoffman-La Roche, Inc.*, 667 F. Supp. 1072 (D.N.J. 1987) 17
Roche Prods, Inc. v. *Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984) 3
Russello v. *United States*, 464 U.S. 16 (1983) 23
Garcia v. *United States*, 469 U.S. 70 (1984) 28

TABLE OF AUTHORITIES – continued

	Page
Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997)	20
Warner-Lambert Co. v. *Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003)	*passim*
Washington Legal Found. v. *Henney*, 202 F.3d 331 (D.C. Cir. 2000)	6

STATUTES

21 U.S.C. § 355(b)(1)	5, 26
§ 355(c)(2)	5, 26
§ 355(c)(3)(D)(ii)	4
§ 355(d)	3, 6
§ 355(j)(2)(A)(i)	6
§ 355(j)(2)(A)(ii)	5
§ 355(j)(2)(A)(iii)	5
§ 355(j)(2)(A)(iv)	4
§ 355(j)(2)(A)(vii)	5, 10, 18, 26, 27
§ 355(j)(2)(A)(viii)	22, 27
§ 355(j)(2)(B)(ii)	5
§ 355(j)(5)(B)(ii)	5, 19
§ 355(j)(5)(B)(iii)	5, 19
§ 505(c)(3)(D)(iii)	18
28 U.S.C. § 1295(a)	19
35 U.S.C. § 154(a)(1)	18
35 U.S.C. § 156(b)(2)	4, 22
35 U.S.C. § 271(e)	*passim*

TABLE OF AUTHORITIES – continued

Page

LEGISLATIVE HISTORY

H.R. Rep. No. 98-857, pt. 1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 ..... 3, 11, 27, 28, 29

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TABLE OF AUTHORITIES – continued

Page

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FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002)..... 20

OPINIONS BELOW

The opinion of the Federal Circuit (App. 1a-44a) was entered on March 28, 2003, and is reported at 324 F.3d 1322 (Fed. Cir. 2003). The order denying the Petition for Rehearing (App. 69a-70a) was entered on May 22, 2003 and is unreported. The decision of the district court (App. 45a-68a) was entered on May 8, 2002, and is reported at 200 F. Supp. 2d 1219 (C.D. Cal. 2002).

JURISDICTION

The Federal Circuit entered its judgment in this case on March 28, 2003, and denied the Petition for Rehearing en Banc on May 22, 2003. On August 13, 2003, the Chief Justice extended the time for filing a petition for writ of certiorari until September 19, 2003. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Section 271(e)(2) of the Patent Act, 35 U.S.C. § 271(e)(2), provides, in relevant part, that:

> It shall be an act of infringement to submit—
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

STATEMENT OF THE CASE

This case raises the important issue of what rights patentees have under the patent litigation provision of the Drug Price Competition and Patent Term Restoration Act of 1984 (the

"Hatch-Waxman Act"), 35 U.S.C. § 271(e)(2), to enforce patents that claim novel methods of using drugs to protect health or to treat illness. In the decision below, the Federal Circuit ruled that the Act affords no protection to method of use patents that claim so-called "off-label" uses—*i.e.*, uses for which the Food and Drug Administration ("FDA") has not approved the drug, but for which physicians can and often do prescribe it—or that protect only one of several FDA approved uses. As a result, the decision below effectively destroys incentives for manufacturers to make the substantial investments necessary to discover and develop new therapeutic and potentially life-saving uses of existing drugs.

The decision in this case is particularly remarkable because all three members of the panel below openly disagreed with the judgment they rendered. Bound by another panel decision issued just months earlier, the panel below upheld dismissal of a patent action that all three judges agreed was authorized by the plain language of § 271(e)(2). In an extraordinary move, each member of panel below wrote or joined a concurring opinion to explain why the earlier and controlling opinion in *Warner-Lambert Co.* v. *Apotex Corp*, 316 F.3d 1348 (Fed. Cir. 2003) is wrong, and why none of the policy arguments *Warner-Lambert* panel relied upon provided a basis for ignoring the statute's plain language.

Despite this sharp division between two panels, the Federal Circuit declined to rehear this case en banc. That refusal leaves in place a controlling interpretation of federal law that, as the panel below cogently explained, is manifestly incorrect. That erroneous interpretation, moreover, was driven by a misguided view of so-called "off-label" use of FDA-approved drugs—a view that failed to recognize that a generic drug manufacturer can, consistent with federal law, seek FDA approval for one use of a drug with knowledge and intent that the drug will be prescribed for "off-label" uses that infringe a valid method of use patent. The Federal Circuit's mis-interpretation of § 271(e)(2) adversely affects the public

health and safety by depriving pioneer drug manufacturers of the financial incentives to research and develop innovative new uses for existing medications. The proper interpretation of § 271(e)(2) is thus an issue of exceptional importance worth of this Court's review.

A. Statutory Background

In the Hatch Waxman Act, Congress sought to strike a careful balance between two competing interests—protecting the patent rights of pioneer drug manufacturers and fostering legitimate generic drug competition. Both of these interests had been adversely affected by 1962 amendments to the Food, Drug, and Cosmetic Act ("FDCA") that required all manufacturers to demonstrate through well-controlled studies that their products are safe and effective for their intended use. 21 U.S.C. § 355(d). By preventing manufacturers from exploiting their patented inventions until the lengthy testing and FDA review process was completed, these requirements deprived pioneer drug manufacturers of years of patent protection on their patents. See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669-71 (1990). At the same time, the costs of the testing and review process were so great that generic versions of numerous name brand drugs remained unavailable years after the patents on those drugs expired. H.R. Rep. No. 98-857, pt. 1, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650. In addition, generic competition was further hampered by the Federal Circuit's 1984 ruling that the manufacture, sale and use of a patented drug constituted an act of infringement even when done solely to perform testing to collect data needed to apply for regulatory approval. See *Roche Prods., Inc.* v. *Bolar Pharm. Co.*, 733 F.2d 858, 862-63 (Fed. Cir. 1984).

The Hatch-Waxman Act responded to these problems in a number of ways. In order to restore the years of patent protection lost as a result of the testing and approval process, the Act authorizes the Patent & Trademark Office to extend the terms of patents on pioneer drugs and methods of using

drugs. 35 U.S.C. § 156. The Act also grants periods of exclusive FDA regulatory approval to manufacturers who invest in the costly safety and efficacy testing necessary to obtain approval of a New Drug Application ("NDA"). 21 U.S.C. § 355(c)(3)(D)(ii).

On the other hand, the Act facilitates generic competition by authorizing the filing of Abbreviated New Drug Applications ("ANDAs") for generic copies of pioneer drugs. The Act permits a generic manufacturer to rely on testing performed by the pioneer, provided the generic product is bioequivalent to the approved pioneer product. *Id.* § 355(j)(2)(A)(iv). The Act also overruled the Federal Circuit's decision in *Bolar* by adding § 271(e)(1) to the Patent Act, which provides that it is not an act of infringement to make, use, offer to sell, or sell a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1).

At the same time that Congress eliminated the economic and legal barriers to legitimate generic drug competition, however, Congress also sought to ensure that such competition did not undermine the patent rights of pioneer drug manufacturers, and the crucial research incentives such patent rights create. Congress clearly recognized that the value of patents on drugs or methods of using drugs is severely undermined once generic versions of the drug enter the market. The system Congress designed to protect patent rights, therefore, seeks to resolve any claim that a generic infringes a patent on a drug or method of use *before* the FDA approves a generic.

Under this system, an NDA holder must give notice to ANDA applicants of its patent rights by listing with the FDA any unexpired patent on an approved drug or on any patent "which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the

manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1) & (c)(2). An ANDA applicant must, in turn, include, as part of its application for FDA approval, a certification:

> with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section–
>
> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

Id. § 355(j)(2)(A)(vii).

If the ANDA applicant files a "paragraph IV" certification, it must give the owner of the patents notice of the ANDA and a statement explaining why it believes the patents are not infringed and/or are invalid. *Id.* § 355(j)(2)(B)(ii). The patentee then has 45 days to sue for infringement. *Id.* § 355(j)(5)(B)(iii). If the patentee sues within that time, the FDA will stay approval of the ANDA for 30 months, or until a court decides either that (1) the patent is infringed and not invalid, in which case the FDA will stay approval until the patent's date of expiration, or (2) the patent is not infringed or is invalid, in which case the FDA will automatically lift its stay. *Id.* If the parties' rights have not been adjudicated, the stay is also automatically lifted after 30 months. *Id.*

To ensure that federal courts can exercise jurisdiction over the infringement actions contemplated by this scheme, the Act also added § 271(e)(2) to the Patent Act. That provision states that:

> It shall be an act of infringement to submit—
>
> . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A).

B. "Off-Label" Use Of FDA-Approved Drugs

Central to the dispute in this case is the practice of so-called "off-label" use of FDA-approved drugs. The FDA approves an NDA only if "well-controlled clinical investigation[s]" demonstrate that the drug is safe and effective for its labeled use. 21 U.S.C. § 355(d). Because an ANDA relies on investigations conducted by an NDA holder, an ANDA applicant can only seek approval for a labeled use the FDA has previously approved. *Id.* § 355(j)(2)(A)(i).

Because the FDA does not regulate the practice of medicine, however, "the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties." *Washington Legal Found.* v. *Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000). Indeed, "[o]ff-label use is not only legal and ethical, but is a common and integral feature of medical practice. The pace of medical discovery runs far ahead of FDA's regulatory machinery, and off-label use is frequently 'state-of-the-art treatment.'" James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 79 (1998). Prescriptions for off-label uses of drugs "may account for more than 25% of the approximately 1.6 billion prescriptions written each year, with some recent estimates running as high as 60%." *Id.* at 80 (internal quotation marks omitted). The FDA itself has recognized that "'unlabeled' uses may be appropriate and

rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature." *Use of Approved Drugs for Unlabeled Indications,* 12 *FDA Drug Bulletin: Information of Importance to Physicians and Other Health Care Professionals* (FDA, Rockville, Md.) Apr. 1982, at 4-5.

Thus, manufacturers can seek approval for one use of a drug with the knowledge and intent that, if approved, the drug will be prescribed for other uses. Moreover, manufacturers often make information about off-label uses of their products available to physicians, for example, by posting independent medical literature on their websites. It is against this regulatory and medical backdrop that petitioner's infringement action arose.

C. Petitioner's Method Of Use Patents

Petitioner holds two patents that claim a method of using brimonidine, a substance originally covered by a patent issued to Pfizer, Inc. In the late 1980s, petitioner began testing brimonidine as a treatment for open-angle glaucoma, an incurable disease that leads to blindness. For decades, medical professionals believed that this disease was caused when watery fluid in the eye fails to drain properly, thereby increasing intraocular pressure ("IOP"). Accordingly, the only known drug therapy for open-angle glaucoma was to lower IOP in an attempt to slow the disease's progression.

After years of expensive research and testing, petitioner demonstrated the drug's safety and efficacy in treating open-angle glaucoma and submitted an NDA for such use of brimonidine in 1995. The FDA approved the NDA the following year. It granted petitioner its five years of regulatory approval exclusivity, as well as the additional six-month exclusivity for conducting pediatric studies.

Beginning in the mid-1990s, researchers, including the named inventors of the patents-in-suit, began to understand that vision loss and blindness may result not only from

elevated IOP, but also from disease of the optic nerve itself. This realization started from the observation that a large percentage of patients with open-angle glaucoma have statistically normal IOP while showing progressive loss of vision, while many people with statistically elevated IOP never develop glaucoma at all. As a result of this research, open-angle glaucoma is now defined as a neurodegenerative disease, instead of a disease of elevated IOP.

At around this same time, scientists working for petitioner discovered that, in addition to its IOP-lowering effects, brimonidine can be used to protect optic nerve cells from dying—*i.e.*, that the drug has neuroprotective qualities. This ground-breaking new use for brimonidine is claimed in the two patents at issue in this suit. Since this discovery, the use of brimonidine as a neuroprotective agent has been widely publicized and accepted by many doctors. As a result, doctors now prescribe brimonidine for its neuroprotective use, and petitioner and others are funding ongoing research to prove the efficacy of brimonidine's neuroprotective use in humans.

D. Petitioner's Infringement Claims

In October, 2001, respondents filed ANDAs with the FDA seeking approval of generic brimonidine. Although there are already dozens of IOP-lowering drugs on the market, including several sold by respondents themselves, their ANDAs sought FDA approval only for brimonidine's use in lowering IOP. Respondents were fully aware, however, that, because large percentages of open-angle glaucoma patients have either normal IOP or do not respond to IOP-lowering treatment, the vast majority of glaucoma patients are candidates for neuroprotective treatment, and that respondents' generic versions of brimonidine can and will be used for the unapproved neuroprotective use claimed in petitioner's patent. In fact, respondents had already taken steps to encourage this use of brimonidine at the time they filed their ANDAs.

Thus, Alcon's website advertises neuroprotection as a glaucoma treatment, both as a general matter and with respect to one of its existing products, which, like petitioner's product, is indicated for use "in lowering intraocular pressure." In addition, Alcon's website lists articles that specifically discuss brimonidine's ability to protect the optic nerve. Similarly, respondent B&L's website promotes brimonidine as a neuroprotective drug to doctors. Through its Center for Contact Lens Research website, B&L distributes to doctors and other eye care professionals research by the one of the named inventors of petitioner's patents regarding brimonidine's neuroprotective effects. This research is presented with B&L's logo prominently displayed and without reference to petitioner, which paid for the research. The website also contains other abstracts on neuroprotection.

Based on the foregoing conduct and the submission of their ANDAs, petitioner sued respondents under § 271(e)(2). Petitioner alleged that, if the FDA approves the ANDAs, respondents will induce infringement of petitioner's patented methods of using brimonidine for neuroprotection.

E. The District Court's Decision

Alcon moved for summary judgment at the very outset of the case, arguing that it could not be liable under § 271(e)(2) because its ANDA sought approval only for use of brimonidine in the reduction of IOP, not the neuroprotective use claimed in petitioner's patents. The district court acknowledged that the record was "sufficient to present a triable issue of fact" concerning Alcon's direct or induced infringement, "or at the least, [to] allow [petitioner] to conduct discovery," App. 53a, and that § 271(e)(2) appeared, by its plain terms, "to address precisely the situation now before the Court." *Id.* at 54a. Nevertheless, the court concluded that "the structure of the Hatch-Waxman Act, its legislative history, and the specific problem that Section 271(e) was meant to address" overrode the statute's plain language. *Id.* at 60a.

In particular, the district court gave dispositive weight to a House Report describing the Act's certification provisions. Although the Act itself requires a certification "with respect to each patent which claims . . . a use for [the] listed drug," 21 U.S.C. § 355(j)(2)(A)(vii), the court believed that the House Report "set forth the process more clearly," App. 61a, and required a certification only for a patent that claimed the same use for which an ANDA applicant seeks FDA approval. *Id.* at 61a-62a. Based on this view of the certification provision, the court held that Congress did not authorize infringement actions where an ANDA does not seek FDA approval of the use claimed in a patent. *Id.* at 63a.

The court also concluded that § 271(e)(2) did not authorize a suit for inducing infringement. It reasoned that the claims that accrue upon the filing of an ANDA are limited to those that would have accrued earlier, but for the "testing" safe harbor created by subsection (e)(1). *Id.* at 63a-64a. The court also opined that future acts of induced infringement were not "sufficiently immediate" to satisfy Article III's "case or controversy" requirement. *Id.* at 66a.[1]

F. The Disposition of Petitioner's Appeal

The court below affirmed. The panel began by rejecting certain jurisdictional theories advanced by respondents or the district court. The panel explained that, by defining the submission of an ANDA as an act of infringement, the statute creates a case or controversy as soon as an ANDA is filed. *Id.* at 14a. While a § 271(e)(2) action for induced infringement depends on future infringing acts, such claims are not so speculative that they contravene Article III. *Id.* at 16a-17a. Summary judgment is thus inappropriate where, as here, a patentee has raised "a genuine issue of material fact

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[1] Respondent B&L filed a summary judgment motion that adopted Alcon's motion *in toto* and also raised additional factual arguments. In granting that motion, the district court relied on its ruling on Alcon's motion and declined to consider the additional issues B&L raised.

with respect to the claim that the ANDA filer will induce infringement of its patent upon approval of the ANDA." *Id.* at 17a. Turning to the merits of this case, however, the panel concluded that it was bound by the decision in *Warner-Lambert*, which held that § 271(e)(2) does not permit an action for induced infringement when the ANDA applicant does not seek FDA approval for the use claimed in the patent.

In rendering that decision, the *Warner-Lambert* panel stated that the statutory language making it an act of infringement to submit an ANDA for a drug "the use of which is claimed in a patent," "is most reasonably interpreted to mean 'the use *listed in the ANDA*.'" 316 F.3d at 1355-56 (emphasis added). It concluded that these additional words could be implied because the statute "recites 'a drug . . . *the* use of which is claimed,'" not a drug "'*a* use of which is claimed,'"or "'*any* use of which is claimed.'" *Id.* (emphasis and elipses in original). The *Warner-Lambert* panel believed that this reading was more consistent with what it perceived to be the purposes of the Act. The *Warner-Lambert* panel feared that an NDA holder could maintain its marketing exclusivity "by regularly filing a new patent application claiming a narrow method of use not covered by its NDA," then using that patent as a "sword" against any competitor's ANDA—a result that would "not advance the purpose of making available 'more low cost generic drugs.'" *Id.* at 1359.

The *Warner-Lambert* panel also based its interpretation on the House Report. The Report referred to "'*controlling use* patents,'" which it defined as use patents "'which claim an indication for the drug for which the applicant *is seeking approval*,'" and stated that an ANDA applicant "'may certify if applicable that one or more of the product or *controlling use* patents are invalid or will not be infringed.'" *Id.* (quoting H.R. Rep. No. 98-857, pt. 1, at 22, *reprinted in* 1984 U.S.C.C.A.N. at 2655 (emphases added by the panel)). According to the *Warner-Lambert* panel, this language from the House Report demonstrates that an ANDA applicant is

required to certify only with respect to a patent that claims the use for which the applicant seeks approval. *Id.* at 1360. This reading of the certification provision, the *Warner-Lambert* panel believed, confirmed its interpretation of § 271(e)(2).

Although bound by this precedent, the panel below nevertheless took the extraordinary step of writing to explain why *Warner-Lambert* was wrongly decided. Judge Schall, joined by Judge Clevenger, explained that, by defining the act of infringement as the filing of an ANDA for a drug "the use of which is claimed in a patent," Congress made clear that the relevant use is not "the use[] stated in the ANDA," but that "claimed in the patent." App. 23a. The fact that Congress used the phrase "controlling use patent" in the legislative reports but not in the statute demonstrated that Congress understood the concept, but "declined to employ that concept when it wrote section 271(e)(2)." *Id.* at 24a. Judge Schall explained that the only difference between an infringement action where the patented method of use is the subject of the ANDA, and one where the patented method of use is not the subject of the ANDA, "is the degree of proof required" to prove infringement. *Id.* at 25a. He found that petitioner's allegations concerning respondents' promotion of brimonidine for neuroprotection were sufficient to state a valid cause of action for induced infringement. *Id.* at 26a. He then explained why the various other provisions of the Hatch-Waxman Act that the *Warner-Lambert* panel cited cast no doubt on § 271(e)(2)'s plain meaning. *Id.* at 28a-38a.

In a separate concurrence, Judge Linn stated that the *Warner-Lambert* panel had improperly allowed its policy preferences to "override the terms of the statute chosen by Congress." *Id.* at 42a. That panel's fear that NDA holders might use method of use patents as swords against ANDA applicants did not justify "read[ing] the words 'the use for which the FDA has granted an NDA' into the statute." *Id.* at 43a. Because there is no indication that the plain language of § 271(e)(2) "does not reflect [Congress's] intent as to the

policy governing applications by generic drug manufacturers to produce drugs that may have patented 'off-label' uses," Judge Linn, too, would have interpreted the statute in accordance with Judge Schall's analysis. *Id.* 44a.

Despite the unanimous and cogent criticism of the *Warner-Lambert* decision by the panel below, the Federal Circuit denied en banc review without explanation.

REASONS FOR GRANTING THE PETITION

The proper interpretation of § 271(e)(2) is an extremely important issue, not only to pioneer and generic drug manufacturers, but to physicians and patients as well. Patent protection is essential to fostering the research and development that leads both to the introduction of new drugs and to breakthrough therapies that use existing medicines in new ways. The Federal Circuit's controlling interpretation of § 271(e)(2), however, essentially destroys patent protection for the latter innovations. By foreclosing pre-ANDA approval infringement actions for patents that claim "off-label" or subsequently approved uses of existing drugs, the Federal Circuit's interpretation of § 271(e)(2) prevents pioneers who develop innovative new uses from recouping the significant investments that underlie such therapeutic breakthroughs. Such postponed litigation can also disrupt medical care and treatment, by creating the risk that generic drugs will be withdrawn from the market after patients have begun using them. Although as a practical matter the Federal Circuit's exclusive jurisdiction precludes the possibility of a circuit split, the extraordinary criticism of the *Warner-Lambert* panel's binding interpretation by all members of the panel below vividly underscores the importance of the issue presented.

Those criticisms, moreover, were well founded. By adding a limiting qualification that appears nowhere in § 271(e)(2) itself, the *Warner-Lambert* panel interpreted the statute in a

manner that is flatly inconsistent with its plain language, its structure and its purpose. None of the rationales the *Warner-Lambert* panel offered—which reflect misconceptions concerning the statute's goals or misuse of its legislative history—justify this erroneous interpretation.

I. PROPER INTERPRETATION OF § 271(e)(2) IS A QUESTION OF EXCEPTIONAL IMPORTANCE TO THE PUBLIC HEALTH AND SAFETY.

The *Warner-Lambert* panel's interpretation of § 271(e)(2) has profound implications for the public health and safety. The *Warner-Lambert* decision denies meaningful patent protection to all owners of method of use patents that claim "off-label" methods of using drugs or that claim an FDA-approved use of any drug that has multiple approved uses. Unless overturned, this interpretation of the statute will significantly impede innovation in the pharmaceutical industry.

A. The Federal Circuit's Controlling Interpretation Of § 271(e)(2) Severely Undermines Financial Incentives For Developing Important New Uses For Existing Drugs And Could Disrupt Patient Care.

A critical aspect of present-day pharmaceutical research is the discovery of new uses for known drugs. Examples of such new uses often make headline news, and result in life-saving and/or life-improving treatments for millions of patients around the nation and the world.[2] As the widespread practice of "off-label" use makes clear, these important new uses "are often discovered after the FDA approves" NDAs for those drugs. See Beck & Azari, *supra* at 79. This is the case because research into these new uses is often prompted by the initial approval of a drug, where clinical safety is established.

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[2] *See e.g.*, Ron Winslow, *Arthritis Drug Celebrex Shows Promise as a Cancer Weapon, The Wall Street Journal* (May 22, 2002), at B1.

Regardless of when they are discovered, these new uses are the future of modern medicine. Due to the enormous expense and time required to develop and obtain approval of new drugs,[3] FDA approval of new molecular entities, or "blockbuster compounds," has been steadily declining, dropping from more than 30 approvals in the late 1990s to only 17 in 2002. Moreover, the majority of these new entities had similar therapeutic qualities to existing drugs or were relatives of previously discovered entities. Thus, "many therapeutic advances result from new uses of already-approved drug compounds or new dosage forms for existing drugs." James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 Cath. U. L. Rev. 433, 481-84 (1986); see also *Eli Lilly & Co.* v. *Generix Drug Sales, Inc.*, 460 F.2d 1096, 1103 (5th Cir. 1972) ("novelty, usefulness and non-obviousness inhere in the true discovery that a chemical compound exhibits a new needed medicinal capability.").

Like petitioner's investigation into the neuroprotective properties of brimonidine, many breakthroughs come from expensive and time-consuming research and development efforts by pioneer manufacturers. Because all drugs "have medical risks," Beck & Azari, *supra* at 72, pioneer manufacturers must perform the same careful studies, and incur many of the same expenses, to develop new uses for FDA-approved drugs as they do to develop and obtain NDAs for new drugs. In this case, for example, petitioner has spent approximately 10 to 15 million dollars researching brimonidine's neuroprotective uses.

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[3] In 2003, the estimated cost for pioneer drug manufacturers to bring new market was over $800 million and took 12 to 15 years. *See* K. I. Kaitin, *Tufts Center for the Study of Drug Development Impact Report* 2003 May/June 5(3).

Pioneer drug manufacturers simply cannot afford to make the substantial investments necessary to develop new uses of drugs if generic versions can enter the market based on FDA approval of an unpatented use. Because manufacturers of generic drugs invest very little in research and development, their products enter the market at dramatically reduced prices. And, because insurance companies, drug formularies and many state laws mandate substitution of generic drugs for pioneer products—regardless of the uses for which the generic was approved—entry of a generic almost immediately eliminates the profit margins that pioneers need to recoup their research and development costs. "The typical steep price decline upon generic entry results in an enormous drop in market share and profits for the pioneer firm," FTC, Prepared Statement Before the Senate Comm. on the Judiciary, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements,* (May 24, 2001),[4] sometimes as much as 75% in just three months. See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food & Drug L.J. 187, 191 (1999) (citing market share loss Syntax suffered three months after Naprosene (R) went off-patent); see also Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), at chp. 3 (finding that pioneers lose 40% of their market on average to generics after patent expiration).

For a variety of reasons, an infringement action brought *after* an FDA-approved generic enters the market does not provide the protection necessary for an innovator to recoup its significant costs. The crucial remedy of a preliminary injunction is illusory at best. First, courts are extremely unlikely to prohibit all market access to a product that has non-infringing uses. See Wheaton, *supra*, at 482. Second,

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[4] Available at http:// www.ftc.gov/os/2001/05/pharmtstmy.htm.

the risk of harm to patients and the public interest will almost always weigh heavily against such relief—as courts have held in infringement cases involving medical devices.[5]

Nor does a damages remedy provide the assurance of recovery necessary to foster innovative new uses of drugs. Because of the typically large discrepancy between the price of pioneer drugs and their generic counterparts, lost profits damages will often be higher than the gross sales of the generic. And because generic manufacturers do not need to raise large amounts of capital and conduct expensive and time-consuming research and development, most lack sufficient assets to restore the lost profits that the pioneer patentee needs to recoup its research and development costs.

Permitting a generic drug to enter the market before infringement issues are resolved, moreover, deprives the pioneer of any economic incentive to conduct the safety and efficacy testing necessary to obtain an NDA for the patented use. If a pioneer conducted such tests, an NDA for the new use would confer on the pioneer, at most, the exclusive right to *label* its product for the new use for a three-year period.

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[5] *See, e.g., Neuromedical Systems, Inc.* v. *Neopath, Inc.*, 1998 WL 264845, at *16 (S.D.N.Y. May 26, 1998) (denying, in case involving medical device, motion for preliminary injunction based, in part, on finding that public interest would be harmed by injunction); *Ethicon Endo-Surgery* v. *U.S. Surgical Corp.*, 855 F. Supp. 1500, 1517 (S.D. Ohio 1994) (denying, in part on public interest grounds, preliminary injunction seeking to enjoin sale of surgical cutter); *GenDerm Corp.* v. *Ferndale Labs., Inc.*, 32 USPQ2d 1567, 1578-79 (E.D. Mich. 1994) (denying, in part on public interest grounds, preliminary injunction seeking to enjoin sale of topical cream); *Hybritech Inc.* v. *Abbott Labs.*, 4 USPQ2d 1001, 1003-04, 1014-15 (C.D. Cal.1987) (denying in part preliminary injunction: "Whatever else the court does, it will not cut off the supply of monoclonal test kits for cancer patients who are now using the Abbott product."), *aff'd*, 849 F.2d 1446 (Fed. Cir.1988); *cf. Reedco, Inc.* v. *Hoffman-La Roche, Inc.*, 667 F. Supp. 1072, 1081 (D.N.J. 1987) (denying, in part on public interest grounds, preliminary injunction seeking to enjoin sale of psoriasis treatment in trademark infringement case).

See 21 U.S.C. § 505(c)(3)(D)(iii). This "exclusive" labeling right, however, is meaningless where a generic version of the drug has already entered the market. Before the NDA for the new use ever issues (and the pioneer is granted its exclusive labeling rights), physicians will have already begun prescribing the generic for the patented new use. The economic demands of patients, insurers, formularies and even state laws ensure that physicians will continue to prescribe generic drugs for the new use after the pioneer obtains its exclusive labeling rights.

Finally, in addition to destroying the economic incentives necessary to spur innovative new uses of existing drugs, the *Warner-Lambert* panel's interpretation of § 271(e)(2) threatens future disruptions of patient care. Although courts likely will not enjoin generic drug sales during the pendency of an infringement action, once infringement of a patent is established, an injunction is ordinarily granted as a matter of course. See Donald S. Chisum, *Chisum on Patents* § 20.04[2] & n.1 (1999) (citing cases). Indeed, the very essence of a patent is the right to exclude others from its use. See 35 U.S.C. § 154(a)(1). Accordingly, generic manufacturers may be forced to withdraw their products after patients have begun using them. Cf. *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 704-07 (D.N.J. 2000) (dismissing assorted public interest-based arguments and entering permanent injunction against future sales of veterinary drug). Changing prescriptions as a result of a withdrawal of a drug from the market can often be challenging to doctors and patients, particularly where it requires alterations in dosage levels and changes to other medications Obviously, these adverse effects will fall more heavily on the poor and elderly.

The Hatch-Waxman Act's patent-related provisions were plainly designed to prevent the foregoing problems. Those provisions ensure that a generic drug covered by a valid method of use patent does not reach the market until *after* the

patent expires, and that any dispute over whether a generic is covered by such a patent is resolved *before* the FDA approves the drug.[6] The Federal Circuit's interpretation of § 271(e)(2) destroys this careful design for all patents claiming "off-label" methods of use, as well as patents that claim only one of several FDA-approved uses for a drug. By doing so, the decision below will chill investment in the research and development necessary to promote innovative new uses of existing drugs—to the ultimate detriment of the nation's health. In short, the proper interpretation of § 271(e)(2) is an exceptionally important question requiring this Court's review.

B. The Concurring Opinions Below Confirm The Importance Of The Issue Presented.

The extraordinary concurring opinions below underscore the importance of the issue presented and the need for this Court's review. Because the Federal Circuit has exclusive jurisdiction over patent appeals, 28 U.S.C. § 1295(a), as a practical matter there can never be a split of authority among the circuits over the proper interpretation of § 271(e)(2). Nevertheless, this Court has granted review of several recent decisions where, as here, the Federal Circuit's dispositive resolution of an important issue of patent law spawned pointed dissents. See, *e.g.*, *Festo Corp.* v. *Shoketsu Kinzoko Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002) (noting four dissenting opinions from en banc decision); *Warner-*

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[6] Where an ANDA applicant does not dispute that its generic drug will infringe a valid patent, FDA approval of the ANDA cannot take effect prior to the expiration of the patent. 21 U.S.C. § 355(j)(2)(A)(vii)(III), 355(j)(5)(B)(ii). Where the applicant does contest the validity or scope of a patent, § 271(e)(2)'s "artificial" act of infringement allows courts to hear and resolve such disputes during the 30-month period that FDA approval of the ANDA is stayed. See *id.* § 355(j)(5)(B)(iii). If the patent is found to be infringed and not invalid during that 30-month period, FDA approval of the drug likewise cannot take effect prior to the patent's expiration. *See id.* § 355(j)(5)(B)(iii)(III); 35 U.S.C. § 271(e)(4).

Jenkinson Co. v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (noting "significant disagreement within" the Federal Circuit in en banc proceeding). Although the Federal Circuit declined to grant en banc review in this case, three judges exhaustively detailed the numerous analytical flaws in the now controlling interpretation of § 271(e)(2) that the *Warner-Lambert* panel rendered.

In addition, the Federal Trade Commission criticized the essentially identical interpretation that the district court rendered in this case. In a study of the drug industry, the FTC opined that the district court's dismissal of Allergan's case was erroneous and should be reversed. The FTC explained that

> "[u]nder the plain language of 35 U.S.C. § 271(e)(2), . . . *all* ANDAs constitute acts of infringement sufficient to establish the existence of a case or controversy with respect to *all* patents that claim any drug or any method of using the drug that may be infringed by generic marketing under an ANDA . . . ."

FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002).[7]

Finally, the judges on the panel below recognized that the *Warner-Lambert* panel's erroneous interpretation frustrates Congress's evident desire to have patent disputes resolved before the FDA approves an ANDA, and deprives both pioneer and generic manufacturers of the important benefits that such pre-approval resolutions provide. As Judge Schall explained, interpreting § 271(e)(2) to permit infringement claims even where the ANDA does not seek FDA approval for the patented method of use

> would benefit both the ANDA applicant and the patentee. The ANDA applicant would benefit by

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[7] Available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

> challenging the scope of a patentee's rights before the patent expires and before the applicant has invested in production and manufacturing facilities in reliance on its approved ANDA. The patentee, in turn, would profit by enforcing its patent rights before a generic drug manufacturer has moved into the market as a competitor. This balance is what Congress intended when it created the artificial act of infringement under section 271(e)(2).

App. 26a-27A; see also *id.* at 44a (Linn, concurring) (recognizing "[t]he importance of this issue").

The legal issue raised in this case thus has profoundly important implications for the public health and safety, and has generated sharp divisions between judges of the Federal Circuit. That issue thus warrants this Court's plenary review.

II. THE FEDERAL CIRCUIT'S CONTROLLING INTERPRETATION OF § 271(e)(2) IS WRONG.

The *Warner-Lambert* panel's interpretation of § 271(e)(2) not only undermines the financial incentives essential to the development of innovative new uses of existing drugs, it flatly contravenes congressional intent. By its plain terms, § 271(e)(2) permits precisely the type of pre-ANDA approval patent litigation that petitioner sought to institute in this case. None of the *Warner-Lambert* panel's rationales for ignoring this plain language withstands scrutiny.

A. The *Warner-Lambert* Panel's Interpretation Is Inconsistent With The Statute's Plain Language.

Section 271(e)(2) makes it an act of infringement to submit an ANDA

> for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submssion is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). In both *Warner-Lambert* and this case, defendants submitted ANDAs for "a drug . . . the use of which is claimed in a patent" that had not expired. The *Warner-Lambert* panel concluded, however, that the statutory phrase "'the use' is most reasonably interpreted to mean 'the use listed in the ANDA.'" 316 F.3d at 1356. Thus, as construed by the *Warner-Lambert* panel, § 271(e)(2) makes it an act of infringement to submit an ANDA "for a drug . . . the use of which is claimed in a patent *and is listed in the ANDA*."

The *Warner-Lambert* panel sought to justify its undisguised amendment of the statutory language by placing critical weight on the statute's use of the definite article "the" before the word "use." It reasoned that, because § 271(e)(2) refers to a drug "'*the* use of which,'" rather than "'*a* use of which'" or "'*any* use of which'" is claimed in a patent, the words "'the use' require antecedent basis; thus, 'the use' refers to a specific 'use' rather than a previously undefined 'use.'" *Id.* (emphases in original). This reasoning is demonstrably wrong.

Congress plainly knew how to distinguish between (1) a use that is patented and (2) a use that is patented *and the subject of FDA approval*. In authorizing extensions for patents on FDA approved drugs or methods of using drugs, Congress provided that the rights derived from any such extension shall, "in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent *and approved for the product*." 35 U.S.C. § 156(b)(2) (emphasis added). Similarly, where an NDA holder lists a patent claiming a method of using the drug, an ANDA submitted for that drug must include a statement that the patent "does not claim a use *for which the applicant is seeking approval*." 21 U.S.C. § 355(j)(2)(A)(viii) (emphasis added). The fact that, in two separate provisions, Congress specified uses that are both patented *and* that are the subject (or not the subject) of FDA approval is fatal to any attempt to

read the additional qualification of an "approved" use into § 271(e)(2).[8] See, *e.g.*, *Russello v. United States*, 464 U.S. 16, 23 (1983) ("when one statutory section includes particular language that is omitted in another section of the same Act, it is presumed that Congress acted intentionally and purposely").

In short, the *Warner-Lambert* panel's interpretation of § 271(e)(2) is inconsistent with—indeed, it adds words to—the plain language of the statute. This clear judicial amendment of statutory language is yet another reason justifying plenary review by this Court. See *Pfaff* v. *Wells Elects., Inc.*, 525 U.S. 55, 60 (1998) (granting certiorari, in part, because the text of the statute the Federal Circuit had interpreted "ma[de] no reference to" the "'substantial completion' of an invention" test that the lower court applied).

B. Interpreting § 271(e)(2) In Accordance With Its Plain Terms Is Consistent With Congressional Intent.

Nor is there any merit to the *Warner-Lambert* panel's conclusion that the plain meaning of § 271(e)(2) is inconsistent with the purposes of the Hatch-Waxman Act. 316 F.3d at 1359. The panel based that conclusion on its mistaken view that an NDA holder "would be able to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not

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[8] In reaching its contrary conclusion, the *Warner-Lambert* panel cited Justice Scalia's reliance on the word "the" in Article II, Section 2 of the Constitution "as narrowing a class to specific 'envisioned' members of the class." 316 F.3d at 1356 (quoting *Freytag* v. *Commissioner*, 501 U.S. 868, 902 (1991) (Scalia, J., concurring)). Justice Scalia emphasized, however, that the Constitution does not "'partake of the prolixity of a legal code,'" *Freytag*, 501 U.S. at 902 (quoting *McCulloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316, 407 (1819)). The Hatch-Waxman Act, by contrast, is a legal code of great prolixity that does "bristle" with "explicit cross-reference[s]," *id.*, to numerous subsections and carefully defined concepts.

covered by its NDA," then "us[ing] § 271(e)(2)(A) as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent." *Id.* Interpreting § 271(e)(2) in accordance with its plain terms, however, does not give rise to such a threat.

In suggesting otherwise, the *Warner-Lambert* panel failed to recognize that an allegation that a manufacturer has filed an ANDA for a drug "the use of which is claimed in a patent" is a necessary, but not a sufficient, predicate to a viable claim of induced infringement. To prevail on such a claim, the patentee must also establish that, "if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense." *Glaxo, Inc.* v. *Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). The patentee must therefore be able to allege, and ultimately prove, not only that an ANDA has been filed for a drug the use of which is claimed in its patent, but also that the applicant's drug will in fact be sold for the patented use because the applicant is encouraging or inducing the patented use or the patented use is the substantial use for the drug. Thus, only an NDA holder that obtains a patent on an unapproved use that has significant applications and utility will have a viable claim under § 271(e)(2).

Protecting patentees that develop commercially important innovative new uses for existing drugs is fully consistent with the purposes of the Act. Contrary to the view of the *Warner-Lambert* panel, see 316 F.3d at 1358, Congress's efforts to foster innovation in the pharmaceutical industry did not begin and end with the restoration of patent protection lost as a result of the lengthy FDA approval process. Rather, the carefully structured patent-related provisions of the Hatch-Waxman Act make clear that Congress also sought to ensure that generic drug competition did not destroy the financial incentives that pioneer manufacturers need to develop new drugs and new uses for existing drug. See *supra* at 18-19 & n.6; see also *Glaxo, Inc.* v. *Novopharm, Ltd.*, 110 F.3d at

1568 (explaining that the Act confers "benefits" on patentees "aside from patent term extension").

The *Warner-Lambert* panel was also plainly wrong in suggesting that pioneer companies that develop new uses for existing drugs make no investment worthy of protection unless and until they conduct the tests necessary to obtain FDA approval of such uses. 316 F.3d at 1359. As noted above, pioneers frequently spend significant amounts of money researching and developing new uses for existing drugs before they begin the studies required for FDA approval of an NDA. See *supra* at 15. The *Warner-Lambert* panel's construction of § 271(e)(2) ensures that such innovators will not have any incentive to make the further investments of time and money necessary to obtain FDA approval of their innovative new use. See *id.* at 15-18.[9]

In addition to denigrating the importance of, and the significant investments that underlie, patents on "off-label" methods of use, the *Warner-Lambert* completely ignored the fact that, in many instances, pioneers obtain patents on one of several FDA-approved uses. It is not uncommon, for example, for a pioneer to obtain a patent and an NDA on an initial use, and then later to obtain an NDA and patent on a second use. In such circumstances, when the patent on the first approved use expires, a generic manufacturer can submit an ANDA for that use and, under the *Warner-Lambert* panel's misconstruction of § 271(e)(2), its generic drug can enter the market and be prescribed for the second, still patented, FDA-approved use. Thus, foreclosing actions under § 271(e)(2) when an ANDA does not seek approval of a patented method of use destroys investments that even the *Warner-Lambert* panel deemed worthy of protection.

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[9] In all events, the exclusive rights that the Patent Act confers do not depend on the amount of money and time spent on research, but on the development of a useful, novel and non-obvious invention.

C. The Patent Certification Provision And Its Legislative History Do not Override The Plain Language Of § 271(e)(2).

Finally, in justifying its interpretation of § 271(e)(2), the *Warner-Lambert* panel placed great weight on the patent certification provision and its legislative history. As noted above, that provision requires a certification:

> with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug *for which the applicant is seeking approval* under this subsection and for which information is required to be filed under subsection (b) or (c) of this section."

21 U.S.C. § 355(j)(2)(A)(vii) (emphasis added). The *Warner-Lambert* panel concluded that the highlighted phrase modifies the word "use," and thereby confirms that § 271(e)(2) applies only when a method of use claim covers the use for which the ANDA filer seeks FDA approval.

The panel's conclusion in this regard is plainly mistaken. First, as Judge Schall explained in his concurring opinion below, App 34a-35a, the certification provision contains two parallel "for which" clauses—"for which the applicant is seeking approval . . . and for which information is required to be filed under subsection (b) or (c)"—both of which necessarily modify the same antecedent. The antecedent for the second clause, however, can only be the "listed drug." Subsection (b) requires the NDA applicant to file certain information concerning "any patent which claims the drug . . . or which claims a method of using such drug." 21 U.S.C. § 355(b)(1). Subsection (c), in turn, refers to "the patent information described in subsection (b)." *Id.* § 355(c)(2). Neither subsection contains an antecedent for "information" that the NDA applicant must file concerning the "use" for which approval is sought. Indeed, the ANDA provisions confirm that the antecedent for the "information" identified in

the second "for which" clause is patent information about the "listed drug." Immediately after the certification provision, subsection (viii) requires a separate statement "if *with respect to the listed drug . . . information was filed* under subsection (b) or (c) of this section for a method of use patent." *Id.* § 355(j)(2)(A)(viii) (emphasis added).

Second, the combination of the certification provision and subsection (viii) refute the *Warner-Lambert* panel's narrow construction of § 271(e)(2). Together, these provisions require one of four certifications *and*, where applicable, a separate statement concerning a method of use patent. Thus, for each patent "which claims the listed drug . . . or which claims a use for such listed drug," the ANDA filer must make a certification

> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, *or*
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; *and*
>
> (viii) if with respect to the listed drug . . . information was filed under subsection (b) or (c) of this section for a method of use patent *which does not claim a use for which the applicant is seeking approval under this subsection*, a statement that the method of use patent does not claim such a use.

Id. § 355(j)(2)(A)(vii)-(viii) (emphases added).

Congress's careful use of the disjunctive with respect to the required certifications and the conjunctive when introducing subsection (viii)'s separate statement requirement makes plain that, even when a listed patent claims a use for which the applicant is not seeking approval, the Act requires *both* a statement that the patent does not claim a use for which

ANDA approval is sought *and a paragraph (IV) certification of noninfringement and/or invalidity*. The fact that Congress required a certification with respect to a patent that claims a use other than the one for which the applicant seeks approval confirms that a § 271(e)(2) infringement action can be brought in such circumstances as well. Had it not intended to permit § 271(e)(2) actions based on patents that claim uses for which the ANDA applicant is not seeking approval, Congress would have required *only* the subsection (viii) statement in such circumstances, not such a statement and an appropriate certification as well.

Ignoring the clear import of these provisions, the *Warner-Lambert* panel relied instead on two passages from the House Report that accompanied the Hatch-Waxman Act. See 316 F.3d at 1359-60. In the first such passage, the House Report states that

> [w]ith respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug *for which the applicant is seeking approval* (hereafter described as a *controlling use* patent), the applicant must certify, in his opinion and to the best of his knowledge, as to one of four circumstances.

H.R. Rep. No. 98-857, pt. 1, at 22, *reprinted in* 1984 U.S.C.C.A.N. at 2655 (emphases added). This legislative history, however, cannot override the plain language of § 271(e)(2) and the clear import of the certification provision and subsection (viii). See *Garcia* v. *United States*, 469 U.S. 70, 75 (1984) ("[O]nly the most extraordinary showing of contrary intentions from [the legislative history] would justify a limitation on the 'plain meaning' of the statutory language"). In fact, as Judge Schall explained, App. 36a-37a, this legislative history simply highlights the fact that Congress knew how to distinguish between patented uses and patented uses for which FDA approval is sought. The fact that Congress knew how to draw this distinction, did so in the legislative history (and, as noted above, in other provisions of

the Act), but did not do so in either § 271(e)(2) or the enacted language of the certification provision refutes, rather than supports, the *Warner-Lambert* panel's interpretation of these provisions.

That panel also relied on an example the House Report provided to illustrate how the certification provision would work. In this passage, the Report states

> [f]or example, the listed drug may be approved for two indications. If the applicant is seeking approval only for Indication No. 1, and not Indication No. 2 *because it is protected by a use patent*, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for Indication No. 2.

H.R. Rep. No. 98-857, pt. 1, at 22, *reprinted in* 1984 U.S.C.C.A.N. at 2655 (emphases added). This passage *confirms* the clear import of subsection (vii)'s certification requirement and subsection (viii)'s statement requirement, and completely refutes the *Warner-Lambert* panel's construction of those subsections. By its plain terms, this passage from the House Report states that where a patent claims a use (or indication) for which the applicant does *not* seek FDA approval, the applicant must nevertheless still "make the appropriate certification *and* a statement explaining that it is not seeking approval for" the patented use. This passage, therefore, provides no basis for foreclosing § 271(e)(2) infringement actions when an ANDA does not seek FDA approval of a patented method of use.

In short, the *Warner-Lambert* panel's controlling construction of § 271(e)(2) is demonstrably wrong. It is inconsistent with the language, structure and purposes of the Hatch-Waxman Act, and will undermine patient health and safety by depriving pioneers of the financial incentives necessary to spur development of breakthrough new uses of existing drugs. This Court should grant a writ of certiorari to correct this important legal error.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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